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1.0 Purpose

This procedure describes the Operation of a peristaltic pump.

2.0 Scope

These pumps will be used in buffer preparation as well as purification at the Advanced Technology Research Facility (ATRF).

3.0 Authority and Responsibility

- 3.1 The Manager, Manufacturing, Technical Operations has the authority to define this procedure.
- 3.2 The Manager, Manufacturing Operations is responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).
- 3.3 Biopharmaceutical Manufacturing personnel are responsible for the implementation of this procedure.
- 3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Materials and Equipment

- 4.1 Masterflex, Tygon, Pharmed Tubing or equivalent.
- 4.2 Stericon buffer bag or suitable collection container.
- 4.3 Appropriate buffer or material to be transferred.

5.0 Procedure

NOTE: Peristaltic pumps are not calibrated equipment. If flow/dispensing/speed verification is required, directions to perform such an operation will be provided in specific Master Production Records (MPR).

- 5.1 Appropriate buffer or material to be transferred.

- 5.1.1 Verify that the tubing is appropriate for the pump being used (see the Operator's Manual located in the Master Equipment File).
- 5.1.2 Verify that the collection containers are large enough to hold the material and are appropriate for the material being transferred (i.e., Sterile, or pyrogen-free if required).
- 5.2 Operation
 - 5.2.1 See the Operator's Manual for the part diagrams and adjustments.
 - 5.2.2 Open the guard or remove the track or remove the cassette, (whichever applies); there are three basic types: guard, track, or cassette. Disengage the rollers using the roller release levers if applicable. Wrap the tubing around the rollers. Reengage the rollers if applicable.
 - 5.2.3 Close the guard or replace the track or replace the cassette (whichever applies).
 - 5.2.4 Connect the ends of the tubing to the desired containers and/or the filters.
 - 5.2.5 Start the pump by turning the Forward/Off/Reverse switch to the desired direction of rotation.
NOTE: Clockwise rotation will ensure longest possible tube life.
 - 5.2.6 Adjust the speed setting dial to achieve the desired flow. It is recommended to start the pump at a slow flow rate and increment slowly to the desired speed.
NOTE: Peristaltic pumps are self-priming.
 - 5.2.7 Stop the pump by turning the Forward/Off/Reverse switch to the central off position.
 - 5.2.8 Open the guard, remove the track, or remove the cassette (whichever applies). Disengage the rollers using the roller release levers if applicable. Unwrap the tubing from around the rollers.
 - 5.2.9 Clamp off the tubing to the containers and disconnect the ends of the tubing from the desired containers and or the filters.
 - 5.2.10 See the Operator's Manual for the care and maintenance.

6.0 References and Related Documents

Watson Marlow Pumps Operating Instruction Manual located in the MEF.

Masterflex Tubing Pumps Operating Instruction Manual located in the MEF.

7.0 Change Summary